# COMMITTEE ON GOVERNMENT REFORM

**TOM DAVIS, CHAIRMAN**

# *MEDIA ADVISORY*

**For Immediate Release**
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**Contact: Robert White/Drew Crockett**
**(202) 225-5074**

## Are FDA and Pharmaceutical Companies Doing Enough for Drug Safety?

*Committee to Examine Post-Approval Surveillance of Vioxx*

**What:** **Government Reform Committee Oversight Hearing: "Risk and Responsibility: The Roles of FDA and Pharmaceutical Companies in Ensuring the Safety of Approved Drugs, Like Vioxx"**

**When:** **THURSDAY, MAY 5, 2005**
**(Immediately Following a 10:00 a.m. Business Meeting)**

**Where:** **ROOM 2154, RAYBURN HOUSE OFFICE BUILDING**

**Background:**

The pain medication known as Vioxx had been on the market for 5 years and been taken by more than 80 million patients (for an annual sales figure of more than $2.5 billion) by the time its manufacturer, Merck & Co., Inc., pulled the drug off the market this past September.

Merck made this decision after its clinical study showed 3.5 percent of subjects taking Vioxx (rofecoxib) had suffered a heart attack or stroke, compared to 1.9 percent of those taking a placebo. But concerns about Vioxx's safety began in 2000, just one year after the Food and Drug Administration (FDA) approved its use. Additional FDA warning labels were required on the medication in 2002.

**The purpose of this hearing is to gain a better understanding of drug safety and the FDA's post-approval surveillance of medications by examining the actions taken by both FDA and Merck as they relate to the drug Vioxx.**

Could more have been done earlier?

Since Merck's withdrawal of Vioxx, the Committee has conducted an investigation into FDA's actions regarding Vioxx and FDA's post-marketing surveillance of drugs. As part of the investigation, the Committee requested documents from Merck to better assess Merck's knowledge of the cardiovascular safety risks of Vioxx, and whether or not they accurately informed the public and physicians of the risk. Merck used over 3,000 field representatives in the nationwide marketing of Vioxx to physicians and medical professionals.

**A review of the documents supplied to the Committee raises questions as to whether Merck was presenting a fair and balanced presentation to physicians on the safety of Vioxx. These include questions regarding the training materials Merck prepared for its sales force to use after the cardiovascular risks of Vioxx became known and before the additional warnings were placed on the label. The Committee will also question FDA and Merck about the length of time it took to add the warnings.**

The investigation has also led the Committee to question the structure of FDA's Center for Drug Evaluation and Research (CDER) and the work of and the relationship between the Office of New Drugs (OND) and the Office of Drug Safety (ODS). OND is a division within CDER that reviews new drug applications. ODS is a separate division within CDER that evaluates the safety of a drug after its approval by conducting epidemiological studies and evaluating adverse event reports.

During the Committee investigation, internal problems between OND and ODS became clear. To address the vulnerabilities in the interaction between OND and ODS, FDA announced the creation of Drug Safety Monitoring Board to monitor the post-marketing risks and benefits of FDA approved drugs, improve how drug safety information is disseminated to physicians and patients by creating a drug safety website, as well as resolving drug safety disputes. The Committee was pleased with the creation of the Drug Safety Monitoring Board but remains concerned with CDER's approach to the post-marketing surveillance of drugs.

**WITNESSES**

Dr. Steven Galson, Director, Center for Drug Evaluation and Research, Food and Drug Administration

*Accompanied by:*
Dr. John Jenkins, Director, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration
*and*

Dr. Paul Seligman, Director, Office of Pharmacoepidemiology, Center for Drug Evaluation and Research, Food and Drug Administration and former Acting Director, Office of Drug Safety

Dennis M. Erb, Ph.D., Vice President of Global Strategic Regulatory Development for Merck & Co., Inc.

John E. Calfee, Resident Scholar, American Enterprise Institute

Dr. Michael Wilkes, MD, PhD, Vice Dean for Medical Education & Professor of Internal Medicine, University of California, Davis

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